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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/020,450      | 12/14/2001  | Guy Michael Miller   | 346392000900        | 1698             |

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 05/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/020,450

Applicant(s)  
Miller et al.

Examiner  
Phyllis Spivack

Art Unit  
1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

Claims 1-57 are presented.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wechter, W.J., U.S. Patent No. 6,048,891.

Wechter teaches the administration of beta, delta and gamma tocopherol or the metabolite, 2,7,8-trimethyl-2-( $\beta$ -carboxyethyl)-6-hydroxychroman, to treat thromboembolic disease, reperfusion injury or ischemic conditions and to prevent neuropathological lesions. See column 34, lines 39-61. Wechter discloses therapeutic concentrations of non-alpha tocopherols that overlap with those presently recited in claims 15-50. Wechter fails to focus on symptoms of a cerebral ischemic conditions, but rather provides a more general teaching of treating thromboembolic diseases. However, one skilled in the neurology art would have been motivated to administer a non-alpha tocopherol to treat cerebral ischemic conditions in view of the teachings of Wechter. Such would have been obvious in the absence of evidence to the contrary because

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non-alpha tocopherols, in particular gamma tocopherol, exhibit antioxidant efficacy in inhibiting low density lipoprotein oxidation, platelet aggregation and arterial thrombogenesis. It would have been reasonable to expect treatment of thromboembolic conditions to result in ameliorating the symptoms of cerebral ischemia.

Claims 1-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chabrier et al., WO 98/09653.

Chabrier teaches the administration of various derivatives of tocopherol, as  $\beta$ -,  $\gamma$ - or  $\delta$ -tocopherol, to treat neurodegenerative conditions as cerebral infarction. See page 1, line 16, and page 6, lines 18-19. Infarction leads to ischemia. The claims differ in that Chabrier's teaching includes the administration of other active principles in addition to the recited tocopherols. However, one skilled in the neurology art would have been motivated to administer non-alpha tocopherols to treat cerebral ischemic conditions in view of Chabrier's disclosure. Such would have been obvious in the absence of evidence to the contrary because these tocopherols are taught to be oxygen reactive free radical trapping substances that are effective in the treatment of cerebral infarction. The open language of the present claims does not preclude the addition of any of a number of other active agents. The selection of optimal concentrations or particular metabolites of non-alpha tocopherols are parameters well within the purview of those skilled in the art through no more than routine experimentation.

No claim is allowed.

Jiang et al., Proceedings of the National Academy of Sciences, is cited to show further the state of the art.

May 3, 2002

Phyllis Spivack

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